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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,928	08/06/2003	Balaji Venkataraman	52761-0110 (286146)	1053
23370	7590	04/22/2004	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 04/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/635,928

Applicant(s)

VENKATARAMAN, BALAJI

Examiner

Michael C. Henry

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-24 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification, while being enabling for the treatment of the mentioned diseases, does not reasonably provide enablement for the prevention of these diseases. First, in claim 15, the applicant claims "A method of treating or preventing a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." The prevention of such diseases is not enabled since the said diseases do not have a single recognized cause. In fact, the aforementioned diseases, are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness. More specifically, some factors or causes that promotes said diseases are

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menopause, smoking, hysterectomy, ovariectomy or cancer chemotherapy, or treatment of the individual with an estrogen, an androgen, an estrogen-androgen combination, an estrogen-progesterone combination, a steroid or a drug that affects the reproductive system. These are only a few of the factors that promote these diseases in people. Therefore, the prevention of the said diseases by one method is not enabled by the instant disclosure. Dependent claims 15-22 are also not enabled for the prevention of the claimed diseases because of the above stated reasons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,10,13-17,20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson et al. (US 6,040,333).

In claim 1, applicants claim “A composition for treating a condition associated with a hormonal change comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6.” Jackson discloses applicant’s composition for treating a condition associated with a hormonal change (menopause) comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, lines 17-36).

In claim 2, applicant claims “ The composition of claim 1, wherein the calcium is in an amount less than 800 mg. Jackson discloses applicant’s composition of claim 1, wherein the calcium is in an amount less than 800 mg (i.e., 200 mg) (see col. 11, table 1, lines 17-36).

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In claim 3, applicant claims “The composition of claim 1, wherein the calcium is in an amount between about 200 mg and 800 mg. Jackson discloses applicant’s composition of claim 1, wherein the calcium is in an amount between about 200 mg and 800 mg (i.e. 300 mg) (see col. 11, table 1, lines 17-36).

In claim 4, applicant claims “The composition of claim 1, wherein the vitamin D is a vitamin D3 and in an amount less than 800 IU. Jackson discloses applicant’s composition of claim 1, wherein the vitamin D is in an amount less than 800 IU (see col. 11, table 1, lines 17-36). It should be noted that although Jackson does not disclose whether the vitamin D is vitamin D3, the examiner considers that the said vitamin is vitamin D3 especially since the said vitamin is used for the same purpose (i.e, treating a condition associated with a hormonal change).

In claim 5, applicant claims “The composition of claim 1, wherein the vitamin D is a vitamin D3 and in an amount between about 300 IU and 500 IU. Jackson discloses applicant’s composition of claim 1, wherein the vitamin D is in an amount between about 300 IU and 500 IU (i.e. 400 IU). (see col. 11, table 1, lines 17-36). It should be noted that although Jackson does not disclose whether the vitamin D is vitamin D3, the examiner considers that the said vitamin is vitamin D3 especially since the said vitamin is used for the same purpose (i.e, treating a condition associated with a hormonal change).

In claim 10, applicant claims “The composition of claim 1, wherein the vitamin B6 is in an amount of between about 10 mg and 100 mg.” Jackson discloses applicant’s composition of claim 1, wherein the vitamin B6 is in an amount of between about 10 mg and 100 mg (i.e. 50 mg) (see col. 11, table 1, lines 17-36).

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In claim 13, applicant claims “The composition of claim 1 further comprising vitamin C in an amount of less than about 200 mg. Jackson discloses applicant’s composition of claim 1 further comprising vitamin C in an amount of less than about 200 mg (i.e. 100 mg) (see col. 11, table 1, lines 17-36).

In claim 14, applicant claims “The composition of claim 1 further comprising iron in an amount of between about 20 mg and 75 mg.” Jackson discloses applicant’s composition of claim 1 further comprising iron in an amount of between about 20 mg and 75 mg (i.e. 18 mg) (see col. 11, table 1, lines 17-36).

In claim 15, applicant claims “A method of treating or preventing a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6.” Jackson discloses applicant’s method of treating a condition associated with a hormonal change (menopause) in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64). Claims 16 and 17, which are dependent on claim 15, are also encompassed by this rejection. It should be noted that although Jackson does not disclose whether the vitamin D is vitamin D3 and vitamin B12 is a hydroxocobalamin, the examiner considers that the said vitamins are vitamin D3 and vitamin B12, especially since the said vitamins are used for the same purpose (i.e, treating a condition associated with a hormonal change).

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In claim 20 applicant claims "The method of claim 15, wherein the composition further comprises vitamin C in an amount of less than 200 mg." Jackson discloses applicant's method of claim 15, wherein the composition further comprises vitamin C in an amount of less than 200 mg (i.e. 100 mg) (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

In claim 21 applicant claims "The method of claim 15, wherein the composition further comprises iron in an amount of between about 20 mg and 75 mg." Jackson disclose applicant's method of claim 15, wherein the composition further comprises iron in an amount of between about 20 mg and 75 mg (i.e. 18 mg) (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

In claim 22 applicant claim "The method of claim 15, wherein the hormonal change is caused by menopause, smoking, hysterectomy, ovariectomy or cancer chemotherapy, or treatment of the individual with an estrogen, an androgen, an estrogen-androgen combination, an estrogen-progesterone combination, a steroid or a drug that affects the reproductive system." Jackson discloses applicant's method of claim 15, wherein the hormonal change is caused by menopause (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-19,23,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US 6,040,333).

In claim 1, applicant claims "A composition for treating a condition associated with a hormonal change comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6."

Claims 4-9, 11, 12, and 23 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3).

Jackson discloses a composition for treating a condition associated with a hormonal change (menopause) comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, lines 17-36).

The difference between applicant's claimed composition and the composition of Jackson is amount or quantity of the components used in the composition and the specific type of vitamin D and B12 (hydroxocobalamin). However, Jackson discloses that vitamin D and vitamin B12 can be used, and the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Jackson's composition and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

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One having ordinary skill in the art would have been motivated to prepare Jackson's composition and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

In claim 15, applicant claims "A method of treating or preventing a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 16-19 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3).

Jackson discloses a method of treating a condition associated with a hormonal change (menopause) in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

The difference between applicant's claimed method and the method of Jackson is amount or quantity of the components used in the composition and the specific type of vitamin D and B12 (hydroxocobalamin). However, Jackson discloses that vitamin D and vitamin B12 can be used, and the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use Jackson's method to treating a condition associated with a hormonal change and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

One having ordinary skill in the art would have been motivated to use Jackson's method to treating a condition associated with a hormonal change and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

In claim 24, applicant claims "A method of treating or preventing a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, hydroxocobalamin and vitamin B6."

Jackson discloses a method of treating a condition associated with a hormonal change (menopause) in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

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The difference between applicant's claimed method and the method of Jackson is amount that applicant uses hydroxocobalamin whereas Jackson is silent about the use of hydroxocobalmin. However, Jackson discloses that vitamin B12 can be used, and hydroxocobalamin is a vitamin B12.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use Jackson's method to treating a condition associated with a hormonal change and to use any type of vitamin B12, such as hydroxocobalamin, since Jackson discloses, in general, that vitamin B12 can be used.

One having ordinary skill in the art would have been motivated to use Jackson's method to treating a condition associated with a hormonal change and to use any type of vitamin B12, such as hydroxocobalamin, since Jackson discloses, in general, that vitamin B12 can be used. This rejection is made in case Jackson the vitamin B12 Jackson used is not hydroxocobalamin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.


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MCH

April 16, 2004.


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1800